

(11) Publication number:

0 218 732
A1

A61K7/16D16B

EUROPEAN PATENT APPLICATION

BEST AVAILABLE COPY

(21) Application number: 85111728.3

(51) Int. Cl. A: A61K 7/16

(22) Date of filing: 17.09.85

(43) Date of publication of application:
22.04.87 Bulletin 87/17

(64) Designated Contracting States:
AT BE CH DE FR GB IT LI LU NL SE

(71) Applicant: BEECHAM INC.
3 Garret Mountain Plaza
West Paterson New Jersey 07424(US)

(72) Inventor: Stier, Roger E.
265 Washington Avenue
Clifton, N. J. 07011(US)
Inventor: Vidra, James D.
RD 1, Box 54-A
Lebanon, N.J. 08833(US)
Inventor: Misek, Bernard
12 Tara Drive
Pomona, N. Y. 10970(US)

(74) Representative: Russell, Brian John et al
European Patent Attorney Beecham
Pharmaceuticals Great Burgh Yew Tree
Bottom Road
Epsom Surrey KT18 5XQ(GB)

DOC

(54) Dentifrices.

(57) A dentifrice composition containing an anticaries agent and an abrasive is produced to which has been added at least one colour indicator which, when the user brushes his or her teeth with the dentifrice, results in a colour change in the dentifrice within the user's mouth after a predetermined period of brushing time has elapsed for the purpose of indicating to the user that he or she has brushed his or her teeth a sufficient length of time.

EP 0 218 732 A1

BEST AVAILABLE COPY

Dentifrices

The present invention relates to a dentifrice, and in particular to a dentifrice in which a buffering system is used to maintain an alkaline pH for a predetermined period of brushing time, after which a colour change occurs due to a lowering of the pH.

Dentifrices in which colour changes occur during use have been previously described, but there has always been a problem in controlling and varying the length of time for such a change to occur. By means of the present invention, the length of time over which the pH of the dentifrice is lowered may easily be varied to produce a desired colour change, and this may be achieved by adjusting the concentration of a buffering system.

According to the present invention there is provided a dentifrice composition comprising an abrasive and a dentally acceptable base, characterised in that the composition includes a buffering system which maintains an alkaline pH for a predetermined period of brushing time, and a colour indicator which, on contact with saliva, causes a colour change in the dentifrice within the user's mouth after a pre-determined period of time has elapsed.

A preferred buffering system in the composition of the invention comprises a combination of sodium phosphate (di-basic) and sodium hydroxide in a ratio sufficient to maintain an alkaline pH for 30-60 seconds of brushing time.

Preferably, two colour indicators are used in combination so that when the user begins brushing, the first colour indicator gives the dentifrice one colour and at the completion of the predetermined period of time for brushing, the second colour indicator gives the dentifrice a different colour in place of the first colour to show the user that he or she has brushed long enough. The second colour indicator is one activated by the lowering of the pH by the saliva of the user.

A preferred pH responsive colour indicator is phenolphthalein, which will show one colour at the beginning of the brushing period and after a predetermined period of brushing time will change colour. The colour change occurs when the pH of the dentifrice is lowered from its initial alkaline pH to the pH of saliva. At that point it shows a different colour to indicate to the user that he or she has brushed a sufficient length of time.

A combination of pH responsive dyes such as phenolphthalein and FD&C Blue # 1, D&C Yellow # 10 and the like may be used in which the dye combination responds to a lowering of the alkaline pH by the saliva. Initially during brushing the phenolphthalein colour will show. After a predeter-

mined period of brushing, the secondary colour will appear as the pH is lowered by the saliva in the mouth of the user, thereby replacing the phenolphthalein colour.

The dentifrices according to the present invention preferably contain 10% to 50% humectant, from 10% to 40% deionized water, from 20% to 40% abrasive such as calcium carbonate, dicalcium phosphate, or silica, from 0.5% to 2.0% binders, from 0.1% to 0.3% sweeteners, from 0.5% to 5.0% flavourants, from 0.005% colourants, from 0.5% to 2.0% surfactants, from 0.20% to 0.60% sodium hydroxide having an ionic strength and a pH value adapted to yield a final pH for the dentifrice within the range of 10.5-11.5 and from 0.70% to 4.3% of a buffer (all percentages being percentages by weight). The dentifrice composition of the present invention may also contain an effective amount of an anticaries agent such as sodium monofluorophosphate, sodium fluoride or stannous fluoride or the like, alone or in combination. The dentifrice composition may also contain a desensitizing agent and/or an antimicrobial agent. When phenolphthalein is used as the colour indicator, the colour of the dentifrice will change from deep pink to white after 30-60 seconds of brushing. When secondary dyes such as D&C Yellow # 10 or FD&C Blue # 1 are also incorporated, the pink colour will disappear and a yellow or blue colour will appear after 30-60 seconds of brushing.

The dentifrice composition of the invention may be in the form of a striped toothpaste. In that case, the core may be white and have a pH of about 11. The coloured stripes, for example blue, are either clear or opaque and contain a suitable pH sensitive dye. The stripes may have a pH of about 7. In this embodiment of the invention the toothpaste initially shows as white in the user's mouth. Upon brushing, the toothpaste turns a colour, for example pink, and after about 30-45 seconds turns white again to indicate to the user that he or she has brushed a sufficient length of time. Alternatively, the white core may have a pH of about 11 and a coloured stripe such as a red stripe having a pH of about 11 may be combined with the white core. On brushing, the dentifrice turns pink and after about 30-45 seconds returns to the white colour as the saliva lowers the pH, as was the case with the white core and blue stripes. When the colour indicator is incorporated into the stripes of a striped gel toothpaste, this may conveniently be done using a dual compartmentalized tube. The colour indicator may also be combined with a second colouring agent if it is desired to have the dentifrice turn a second

colour other than white at the completion of the predetermined brushing period.

The surfactant in the composition of the present invention is preferably a low foaming material, such as an alkali metal salt of a fatty alcohol sulphate, alkane sulphonate and/or amine oxide, - (and a particularly preferred surfactant is the sodium salt of lauryl alcohol sulphate. The concentration of surfactant is preferably about 1.15%.

The following examples illustrate the present invention:

BEST AVAILABLE COPY

5 Example 1

A dentifrice according to the present invention was prepared by combining the ingredients set forth below according to known conventional techniques:

<u>Ingredients</u>	<u>% w/w</u>
Glycerine	30.350
Sodium carboxymethylcellulose	1.350
Veegum F	1.000
Deionized water	24.890
Sodium monofluorophosphate	0.760
Sodium saccharin	0.250
Phenolphthalein solution	1.000
Sodium hydroxide solution	0.250
Calcium carbonate	38.000
Flavourants	1.000
Sodium lauryl sulfate	1.500
TOTAL	100.000

Example 2

40 A dentifrice according to the present invention was prepared by combining the ingredients set forth below according to known conventional techniques:

45

50

55

Ingredients% w/w

Glycerine	30.350
Sodium carboxymethylcellulose	1.350
Veegum F	1.000
Deionized water	24.890
Sodium monofluorophosphate	0.760
Sodium saccharin	0.250
D&C Yellow #10 dye	0.005
Phenolphthalein solution	1.000
Sodium hydroxide solution	<u>0.250</u>

TOTAL 100.000

Example 3

A striped dentifrice according to the present invention was prepared by combining the ingredients set forth below according to known conventional techniques:

30

35

40

45

50

55

BEST AVAILABLE COPY

<u>Ingredients</u>	<u>% w/w</u>
Glycerine	25.830
Sodium carboxymethylcellulose	1.350
Veegum F	1.000
Deionized water	24.890
Sodium monofluorophosphate	0.760
Sodium saccharin	0.250
Phenolphthalein solution	1.000
Sodium hydroxide solution	0.510
Calcium carbonate	38.000
Flavourants	1.000
Sodium lauryl sulfate	1.150
Dibasic sodium phosphate (anhydrous)	4.260
TOTAL	<u>100.000</u>

and adding thereto a striping material prepared by
combining the ingredients set forth below accord-
ing to known conventional techniques:

35

40

45

50

55

<u>Ingredients</u>	<u>% w/w</u>
Polyethylene glycol 400	3.000
Sodium carboxymethyl cellulose	0.900
Calcium carrageenan	0.250
Deionized water	16.840
Sodium monofluorophosphate	0.760
Sorbitol 70%	62.000
Sodium benzoate	0.200
Sodium saccharin	0.200
Sodium silicate solution	0.200
Silica	13.500
Titanium dioxide	1.000
Sodium lauryl sulfate	1.150
TOTAL	100.000

The preparation of dentifrices including striped dentifrices is well known in the art. U.S. Patent Nos. 3,996,863, 3,980,767, 4,328,205 and 4,358,437, describe toothpastes and methods or production thereof which may be utilized for production of the dentifrices according to the present invention.

Claims

1. A dentifrice composition comprising an abrasive and a dentally acceptable base, characterised in that the composition includes a buffering system which maintains an alkaline pH for a predetermined period of brushing time, and a colour indicator which upon contact with saliva causes a colour change in the dentifrice within the user's mouth after a predetermined period of time has elapsed.

2. A composition according to claim 1, in which the colour indicator is a material showing one colour at alkaline pH and a different colour after the predetermined period of brushing time has elapsed resulting from the lowering of pH by the saliva of the user.

3. A composition according to claim 1 or 2 wherein the colour indicator is phenolphthalein.

30 4. A composition according to any one of claims 1 to 3 wherein two colour indicators are incorporated in the composition, the first colour indicator showing its colour at an alkaline pH and the second colour indicator showing its colour after
35 the predetermined period of brushing time has elapsed resulting from lowering of the pH by the saliva of the user.

5. A composition according to claim 4, wherein the two colour indicators are phenolphthalein and
40 D&C Yellow # 10.

6. A composition according to any one of claims 1 to 5 wherein the buffering system is sodium phosphate (dibasic)-sodium hydroxide combination in an amount sufficient to maintain an
45 alkaline pH for 30-60 seconds of brushing time.

7. A composition according to any one of claims 1 to 6 in which is included an anticaries agent selected from sodium monofluorophosphate, sodium fluoride and stannous fluoride.

50 8. A composition according to any one of claims 1 to 7 wherein the abrasive is calcium carbonate, dicalcium phosphate or silica.

9. A composition according to any one of claims 1 to 8 in the form of a striped toothpaste
55 having a central white core and pastel or coloured stripes that are either clear or opaque, the core having a pH of about 11 and the stripes containing a pH sensitive dye and having a pH of about 7.

10. A composition according to any one of claims 1 to 8 in the form of a striped toothpaste having a white central core and pastel or coloured stripes that are either clear or opaque, the white

central core having a pH of about 11 and the stripes containing at least one colour indicator and having a pH of about 11.

5

BEST AVAILABLE COPY

10

15

20

25

30

35

40

45

50

55

7



European Patent
Office

EUROPEAN SEARCH REPORT

Application number

EP 85 11 1728

DOCUMENTS CONSIDERED TO BE RELEVANT			
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl.4)
X	FR-A-1 576 570 (ASSAL et al.) * Page 1, line 10 - page 2, line 24 *	1-10	A 61 K 7/16
X	--- EP-A-0 003 855 (ASSAL et al.) * Claims *	1,2,4,7,8	
X	--- CHEMICAL ABSTRACTS, vol. 96, no. 12, March 1982, page 411, abstract no. 91675v, Columbus, Ohio, US; & RO - A - 71 000 (INTREPRINDEREA DE MEDICAMENTE, BUCURESTI) 16-06-1980 * Abstract *	1,2	
X	--- US-A-4 132 770 (BARTH) * Claims; column 5, line 27; column 7, lines 34-36 *	1,2	TECHNICAL FIELDS SEARCHED (Int. Cl.4)
X	--- US-A-4 223 003 (SCHELLER) * Claims; column 3, line 22 - column 4, line 25; examples *	1-4,6-8	A 61 K 7/00
X	--- US-A-1 717 723 (McCALL) * Claims *	1-4	
Y	--- EP-A-0 076 563 (BEECHAM) * Claims; example; page 3, lines 17-20 *	1,9,10	
The present search report has been drawn up for all claims			
Place of search THE HAGUE		Date of completion of the search 30-06-1986	Examiner WILLEKENS G.E.J.
CATEGORY OF CITED DOCUMENTS			
X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document		T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons & : member of the same patent family, corresponding document	